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June 11, 2004

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June 11, 2004 — Date
David L. Parker

MS Appeal Briefs
Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

Re: *SN 09/415,890 entitled "Pharmacologically Acceptable Solvent Vehicles" by Andersson*
Our ref: UTXC:528--1 Client ref: MDA96-033 CON1

Commissioner:

Enclosed please find the following for filing in the above-referenced patent application:

1. Appeal Brief, with Appendices A and B (consisting of Exhibits 1-4) (original and three copies);

2. $165 check as the fee for filing the Appeal Brief; and

3. A return postcard to acknowledge receipt of these materials. Please date stamp this postcard and return it by mail.

If the check is inadvertently omitted, or the amount is insufficient, or should any additional fees under 37 C.F.R. §§ 1.16 to 1.21 be required for any, the Commissioner is authorized to deduct said fees from Fulbright & Jaworski Account No.: 50-1212/UTXC:528--1.

Very truly yours,

David L. Parker
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June 11, 2004
Date

David L. Parker

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:
Borje S. Andersson

Serial No.: 09/415,890

Filed: October 8, 1999

For: PHARMACOLOGICALLY ACCEPTABLE SOLVENT VEHICLES

Group Art Unit: 1616

Examiner: Neil Levy

Atty. Dkt. No.:UTXC:528--1/DLP

APPEAL BRIEF

MS Appeal Briefs
Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

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Sir:

Appellants hereby submit an original and two copies of this Appeal Brief to the Board of Patent Appeals and Interferences in response to the final Office Action dated January 26, 2004. The Notice of Appeal was filed on May 21, 2004, and received in the Patent and Trademark Office on May 24, 2004, making this Appeal Brief due on July 24, 2004.

The fee for filing this Appeal Brief is $165; a check is enclosed. If the check is inadvertently omitted, or the amount is insufficient, or should any additional fees under 37 C.F.R. §§ 1.16 to 1.21 be required for any reason relating to the enclosed materials, or should an overpayment be included herein, the Commissioner is authorized to deduct or credit said fees from or to Fulbright & Jaworski L.L.P. Account No.: 50-1212/UTXC:528--1.

Please date stamp and return the attached postcard as evidence of receipt.

I. REAL PARTY IN INTEREST

The real party in interest is the assignee, Board of Regents, The University of Texas System, Austin Texas.

II. RELATED APPEALS AND INTERFERENCES

There are no interferences or appeals for related cases.

III. STATUS OF THE CLAIMS

Claims 94-99 and 106-150 are currently pending, with claims 94-96, 106-115, 123-132, 138-140 and 144-149 currently withdrawn as being directed to a non-elected invention and species with no currently allowable generic or linking claim. Claims 97-99, 116-122, 133-134, 141-142 and 150 are currently subject to rejection. No rejection has been entered with respect to the remaining claims 135-137 and 143. Appellants are appealing the final rejection of claims 97-99, 116-122, 133-134, 141-142 and 150. A copy of the claims on appeal, as well as the other pending claims, is attached as Appendix A.

IV. STATUS OF AMENDMENTS

Appellants sought an amendment after final to address the section 112, second paragraph, rejection of claims 98 and 116, but the Examiner refused to enter and consider the proposed amendment. Concurrently herewith, Appellants have cancelled claim 98. Thus, Appellants elect to challenge the rejection of claim 116 on appeal.

V. SUMMARY OF THE INVENTION

The present invention is directed to a method for making a solvent vehicle for use in solubilizing drugs, particularly relatively insoluble drugs, through the application of a process such as embodied in claim 97, which reads as follows:

> 97. A method for preparing a pharmaceutically acceptable solvent vehicle, the method comprising:
>
> (a) obtaining a pharmaceutically acceptable dipolar aprotic solvent and/or acid;
>
> (b) mixing the dipolar aprotic solvent and/or acid in a pharmaceutically acceptable aqueous secondary solvent;
>
> (c) removing more than 50% of the dipolar aprotic solvent and/or acid and aqueous secondary solvent; and
>
> (d) reconstituting the solvent vehicle by the addition of a pharmaceutically acceptable aqueous solvent.

The dependent claims further specify particular types of solvents or acid as well as the inclusion of lipids, such as in the form of lipid emulsions and in particular soybean emulsion.

VI. ISSUES ON APPEAL

The issues addressed in this appeal include:

a) Whether claim 116 is indefinite under 35 U.S.C. §112, second paragraph;

b) Whether the subject matter of claims 97-99, 116-122, 133-134, 141-142 and 150 is obvious under 35 U.S.C. §103(a) over Szoka, U.S. 5,549,910 (the '910 patent, Exhibit 1) or Szoka, U.S. 5,277,914 (the '914 patent; Exhibit 2) as explained by Corbiere, U.S. 4,794,117 (Exhibit 3) or Smith et al., U.S. 5,006,595 (Exhibit 4).

VII. GROUPING OF THE CLAIMS

With respect to the obviousness rejection, claims 117-122 are each considered to be separately patentable. Further, claim 116 is considered to be separately patentable, as is claim 150. Separate argument for the foregoing claims are presented hereinbelow.

VIII. ARGUMENT

A. The rejection of claims 98 and 116 under 35 U.S.C. § 112, second paragraph, is inappropriate

1. Summary of Rejection

The Final Action first rejects dependent claims 98 and 116 under 35 U.S.C. § 112, second paragraph, taking the position that the language is open to wide interpretation in that it is said to be unclear if applicant intends 1) all water through acetic acid, or 2) a lipid solution or 3) any one of water through lipid solution. The Action continues by taking the position that claim 98 lacks clear antecedent basis in claim 97 and concludes by noting that "one would not at first glance consider a lipid solution of claim 98 to be an aqueous solution" as required by claim 97.

2. Appellant's Remarks

In response, Appellant contends that the interpretation of claim 116 is straightforward and is somewhat surprised at the position taken by the Action. Independent claim 97 specifies "mixing a dipolar aprotic solvent or acid in a pharmaceutically acceptable aqueous secondary solvent." Claim 116 then specifies that the aqueous solvent can include an aqueous lipid emulsion, water, a saline solution, a dextrose solution, glacial acetic acid or a lipid solution. Nothing earth-shattering here. The fact that an aqueous solution can include a lipid solution is

not unusual. An oil-in-water emulsion is one example, a water-in-oil emulsion is another example and another example is lipid micelles.

For the foregoing reasons, the Board is requested to overturn the Action's rejection of claim 116 under § 112, second paragraph.

B. Rejection of Claims 97-99, 116-122, 133-134, 141-142 and 150 as Obvious over the Art

1. Summary of Rejection

The Examiner takes the position that the Szoka patents teach the use of a dipolar aprotic solvent, DMSO, to solubilize a lipophilic drug such as pimaricin, mixing the solubilized drug with a lipid solution and then removing the solvent by dialysis or centrifugation. See Action dated April 24, 2003. The Final Action included the further references of Smith (Exhibit 4) and Corbiere (Exhibit 3), which were said to teach reconstitution of a dosage composition.

2. Appellant's Remarks

a) Substantial evidence required to uphold the examiner's position

Findings of fact and conclusions of law by the U.S. Patent and Trademark Office must be made in accordance with the Administrative Procedure Act, 5 U.S.C. § 706(A), (E), 1994. *Dickinson v. Zurko*, 527 U.S. 150, 158 (1999). Moreover, the Federal Circuit has held that findings of fact by the Board of Patent Appeals and Interferences must be supported by "substantial evidence" within the record. *In re Gartside*, 203 F.3d 1305, 1315 (Fed. Cir. 2000). In *In re Gartside*, the Federal Circuit stated that "the 'substantial evidence' standard asks whether a reasonable fact finder could have arrived at the agency's decision." *Id.* at 1312.

Accordingly, it necessarily follows that an Examiner's position on Appeal must be supported by "substantial evidence" within the record in order to be upheld by the Board of Patent Appeals and Interferences.

b) The standard for obviousness

In order to establish a *prima facie* case of obviousness, three basic criteria must be met: (1) there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings; (2) there must be a reasonable expectation of success; and (3) the prior art reference (or references when combined) must teach or suggest all the claim limitations. *Manual of Patent Examining Procedure* § 2142. Moreover, the teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on Applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 U.S.P.Q. 2d 1438 (Fed Cir. 1991). When "the motivation to combine the teachings of the references is not immediately apparent, it is the duty of the examiner to explain why the combination of the teachings is proper." MPEP § 2142.

c) No Proper Prima Facie Rejection Made

It is Appellant's position that the Examiner has failed to make out a *prima facie* obviousness rejection over the references, alone or in combination, which have not been shown to teach or suggest each of the elements of the claims. The Examiner has failed to demonstrate how the Szoka patents teach or suggest removing more than 50% of the dipolar aprotic solvent and/or acid ***and aqueous secondary solvent***. On the contrary, these patents appear to teach away from "reconstituting" the solvent vehicle through the addition of a pharmaceutically acceptable aqueous solvent. Furthermore, the Examiner has failed to demonstrate how the secondary references are properly combinable, and, if they are, how they are combinable so as to remedy the shortcomings of the primary references. We contend that they are not combinable and, even if they are, they fail to make out a *prima facie* rejection.

Turning first to Szoka '914, Exhibit 2,[1] this patent concerns solubilizing drugs such as pimaricin in a dipolar aprotic solvent and lipids for the purpose of forming liposomal drugs. See, *e.g.*, col. 3, lns 5-16, and para. bridging cols. 4 and 5. Here, it is stated merely that the liposome suspension may be "dialyzed or otherwise concentrated, if desired." See, col. 3, ln 15-16; col. 5, lns 6-7. This concept is expanded upon in col. 6, at lines 4-7, where it is stated that:

> If desired, the liposome or lipidic particle suspensions obtained may be concentrated by standard techniques, including centrifugation, dialysis, diafiltration, counter current dialysis, and the like.

It is submitted first that this in no way constitutes a teaching to remove at least 50% of ***both*** the dipolar aprotic solvent or acid ***and*** at least 50% of the aqueous secondary solvent volume. For example, dialysis *per se* might be expected to remove more than 50% of the dipolar solvent or acid, which is shown in Example 3 at col. 12, lines 42-58, where it is disclosed that suspensions were dialyzed against 2 changes of 100 volumes of distilled water. However, while such dialysis would be expected to remove virtually all of the DMSO, it would not be expected to remove any of the aqueous secondary solvent, much less more than 50% of it.

Similarly, while the Szoka patents make a passing reference to "concentration" by dialysis, *etc.*, they do not appear to provide any further teaching in this regard. Yet, the patents do teach that the compound should be dissolved in the original aqueous phase "at a concentration appropriate for the desired compound:lipid ratio," (col. 5, lns 31-34) which suggests that the patent contemplates that ultimately only minor concentration adjustments will be required, if any. This, of course, argues against removal of more than 50% of the of the aqueous solvent. Indeed, in Example 5, the materials made in accordance with Example 3 (wherein the liposomal

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[1] In that both of the Szoka patents have the same specifications, Appellant will direct its comments to only the '914 patent, for convenience sake.

drug suspension was not concentrated) was used directly in animal studies. Accordingly, while Szoka makes a passing reference to concentration by dialysis, there is no teaching or suggestion of removal of more than 50% of the aqueous solvent and, at best, the patent contemplates only minor adjustments in aqueous amounts in the suspended liposomal formulation.

Moreover, the Examiner has also failed to point out where in the Szoka patents there is any teaching or motivation with respect to "***reconstituting*** the solvent vehicle [from which more than 50% of the aprotic solvent or acid and aqueous secondary solvent has been previously removed] by the addition of a pharmaceutically acceptable aqueous solvent." Appellants have been unable to identify any such suggestion or motivation. On the contrary, the Szoka patents appear to contemplate merely using dialysis to effect a buffer change and remove contaminants and minor changes in concentration of materials. It would appear antithetical to the teachings of Szoka to add back additional aqueous solvent to the dialyzed materials as this would defeat the purpose of dialysis concentration.

Szoka teaches away from the addition of further aqueous solution following "concentration" in other ways as well: a principal goal of Szoka is to achieve "high concentrations of liposomes" (see, e.g., col. 2, line 68). Thus, when the passage regarding "concentrated" at col. 3, lns 15, is read in light of the passage in the previous paragraph regarding "high concentration of liposomes," it is evident that one of skill would not seek to add back additional aqueous solvent following concentration as that would defeat the purpose of the invention.

d) The Secondary References are Insufficient and the Examiner has failed to Explain How they are Properly Combinable

The secondary references, cited for the first time in the Final Action, are of no assistance to the Examiner as they are either irrelevant, as in the case of Corbiere (Exhibit 3) or directed to

entirely different types of formulations that Szoka, as in the case of Smith (Exhibit 4), and thus are inapplicable and not combinable with Szoka.

With respect to the Corbiere patent, the Final Action directs us to col. 4, lns 28-57, which is said to teach reconstitution of a dosage composition. The Action is presumably relying on the excerpt at lines 36-38, which states that the "resulting mixture may be packed in unit dosages or lyophilized in order to be redissolved at the time of use." However, this statement clearly is intended merely to refer to the specific formulation there – a formulation of polyethylene glycol (PEG) intended for direct application to the eye. There is no mention of liposomes, no mention of lipids, and no mention of the need to remove the PEG solvent – on the contrary, Corbiere desires to keep the PEG solvent present rather than remove it.

Moreover, the Examiner has failed to explain how Corbiere is properly combinable with Szoka. Szoka concerns liposomal drug formulations and there is simply no basis in Szoka for concluding that it would be desirable to add additional aqueous solution to the composition after removing the solvent by dialysis – this would have the undesirable effect of further diluting the liposomes contrary to the goal of Szoka. Moreover, with respect to the Examiner's "unit dosage" argument, there is no suggestion from Szoka that the liposomal formulations it teaches can be dried, such as by lyophilization, and reconstituted in manner that would retain the integrity of the liposomes so important to Szoka.

The Smith patent is no more relevant than Corbiere. Smith teaches the preparation of polyvinylpyrrolidone/drug compositions and simply states that the compositions can be evaporated as a dry powder and redissolved in water. See, *e.g.*, col. 3, lines 63-67. As with Corbiere, the Examiner has failed to explain how the reference teaches or suggests the present invention or how it is properly combinable with Szoka. Appellants submit that Smith is not

relevant and not properly combinable for the same reasons discussed above with respect to Corbiere.

Claims 117-122, 134

Claims 117 – 122 present additional patentable features that the Final Action has failed to even attempt to address. For one thing, each of these claims require the inclusion of an aqueous lipid emulsion in the aqueous secondary solvent. Of course, a lipid emulsion is distinct from the type of lipids (phospholipids) that are employed for the liposomes taught or suggested by the art.

Similarly, claims 119 – 120, 122 and 134 make reference specifically to soybean emulsions, and the Action has failed to point out where in the art references this aspect is taught or suggested.

Furthermore, claim 121 makes reference to "at least one vegetable oil" and the Action fails to point out where this aspect is taught or suggested by Szoka.

Claim 150

Claim 150 specifies the use of an acid, in particular glacial acetic acid, together with a lipid emulsion. The Action has failed to point out how the art teaches or suggests this aspect.

For the foregoing reasons, the Examiner is requested to reconsider and withdraw the rejection, and permit applicant the right to reintroduce the withdrawn claims.

IX. CONCLUSION

Appellant has provided arguments that overcome the pending rejections. Appellant respectfully submits that the Final Official Action's conclusions that the claims should be rejected are unwarranted. It is therefore requested that the Board overturn the Final Action's rejections.

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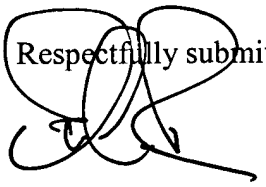
Respectfully submitted,



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Date: June 11, 2004

APPENDIX A

1.-93. (Cancelled)

94. (Withdrawn) The method of claim 93, where the acid is acetic acid.

95. (Withdrawn) The method of claim 93, where the dipolar aprotic solvent and/or acid is virtually eliminated from the solvent vehicle.

96. (Withdrawn) The method of claim 93, where removing the dipolar aprotic solvent and/or acid is by lyophilization.

97. (Previously Presented) A method for preparing a pharmaceutically acceptable solvent vehicle, the method comprising:

(a) obtaining a pharmaceuctically acceptable dipolar aprotic solvent and/or acid;

(b) mixing the dipolar aprotic solvent and/or acid in a pharmaceutically acceptable aqueous secondary solvent;

(c) removing more than 50% of the dipolar aprotic solvent and/or acid and aqueous secondary solvent; and

(d) reconstituting the solvent vehicle by the addition of a pharmaceutically acceptable aqueous solvent.

98. (Cancelled)

99. (Previously Presented) The method of claim 97, further comprising the step of dissolving pimaricin in said dipolar aprotic solvent and/or acid prior to mixing in a pharmaceutically acceptable aqueous secondary solvent.

100.-105. (Cancelled)

106. (Withdrawn) The method of claim 93, wherein the dipolar aprotic solvent or acid is eliminated.

107. (Withdrawn) The method of claim 93, wherein the removing dipolar aprotic solvent or acid removes 95% of the dipolar aprotic solvent or acid.

108. (Withdrawn) The method of claim 107, wherein the removing dipolar aprotic solvent or acid removes 99% of the dipolar aprotic solvent or acid.

109. (Withdrawn) The method of claim 93, wherein said aprotic solvent comprises N,N-dimethylacetamide, castor oil, dimethylsulfoxide, 1,2,-propylene-diol, glycerol or polyethylene glycol-400.

110. (Withdrawn) The method of claim 109, wherein said aprotic solvent comprises N,N-dimethylacetamide.

111. (Withdrawn) The method of claim 109, wherein said aprotic solvent comprises castor oil.

112. (Withdrawn) The method of claim 109, wherein said aprotic solvent comprises dimethylsulfoxide.

113. (Withdrawn) The method of claim 109, wherein said aprotic solvent comprises 1,2,-propylene-diol.

114. (Withdrawn) The method of claim 109, wherein said aprotic solvent comprises glycerol.

115. (Withdrawn) The method of claim 109, wherein said aprotic solvent comprises polyethylene glycol-400.

116. (Previously Presented) The method of claim 97, wherein said secondary solvent comprises aqueous lipid emulsion, water, saline solution, dextrose solution, glacial acetic acid, or lipid solution.

117. (Previously Presented) The method of claim 116, wherein said secondary solvent comprises an aqueous lipid emulsion.

118. (Previously Presented) The method of claim 117, wherein said aqueous lipid emulsion comprises emulsified fat particles of about 0.4 micron in diameter.

119. (Previously Presented) The method of claim 117, wherein said aqueous lipid emulsion comprises an aqueous soy bean lipid emulsion.

120. (Previously Presented) The method of claim 119, wherein said aqueous soy bean lipid emulsion comprises soy bean oil, lecithin, glycerin and water.

121. (Previously Presented) The method of claim 117, wherein said aqueous lipid emulsion comprises a lipid component that includes at least one vegetable oil and at least one fatty acid.

122. (Previously Presented) The method of claim 121, wherein said lipid component comprises at least about 5% by weight soybean oil and at least about 50% by weight fatty acids.

123. (Withdrawn) The method of claim 116, wherein said secondary solvent comprises water.

124. (Withdrawn) The method of claim 116, wherein said secondary solvent comprises saline solution.

125. (Withdrawn) The method of claim 116, wherein said secondary solvent comprises dextrose solution.

126. (Withdrawn) The method of claim 125, wherein said dextrose solution comprises 5% to 70% dextrose in water.

127. (Withdrawn) The method of claim 126, wherein said dextrose solution comprises 5% or 10% dextrose solution.

128. (Withdrawn) The method of claim 116, wherein said secondary solvent comprises glacial acetic acid.

129. (Withdrawn) The method of claim 93, wherein said secondary solvent comprises a lipid solution.

130. (Withdrawn) The method of claim 93, wherein said secondary solvent comprises a parenteral infusion fluid.

131. (Withdrawn) The method of claim 93, wherein said solvent vehicle comprises anhydrous N,N-dimethylacetamide and polyethylene glycol-400.

132. (Withdrawn) The method of claim 93, wherein said solvent vehicle comprises glacial acetic acid and polyethylene glycol-400.

133. (Previously Presented) The method of claim 97, wherein said solvent vehicle comprises anhydrous N,N-dimethylacetamide and aqueous lipid.

134. (Previously Presented) The method of claim 133, wherein said aqueous lipid is an aqueous soy bean lipid emulsion comprising soy bean oil, lecithin, glycerin and water.

135. (Previously Presented) The method of claim 134, wherein said solvent vehicle comprises anhydrous N,N,-dimethylacetamide and an aqueous soy bean lipid emulsion comprising soy bean oil, lecithin, glycerin and water in a 1:10 volume ratio.

136. (Previously Presented) The method of claim 134, wherein said solvent vehicle comprises anhydrous N,N,-dimethylacetamide diluted with 9 volumes 20% of an aqueous soy bean lipid emulsion comprising soy bean oil, lecithin, glycerin and water.

137. (Previously Presented) The method of claim 134, wherein said solvent vehicle further comprises normal saline or 5% dextrose solution.

138. (Withdrawn) The method of claim 93, wherein said solvent vehicle comprises anhydrous N,N-dimethylacetamide, polyethylene glycol-400 and 1,2-propylene diol.

139. (Withdrawn) The method of claim 93, wherein said solvent vehicle comprises anhydrous N,N-dimethylacetamide, polyethylene glycol-400, 1,2-propylene diol and dimethylsulfoxide.

140. (Withdrawn) The solvent vehicle of claim 139, wherein said solvent vehicle comprises anhydrous N,N,-dimethylacetamide, polyethylene glycol-400, 1,2-propylene diol and dimethylsulfoxide in equal volume ratios.

141. (Previously Presented) The method of claim 97, wherein said vehicle comprises glacial acetic acid, and wherein said vehicle further comprises anhydrous N,N,-dimethylacetamide, dimethylsulfoxide or an aqueous soy bean lipid emulsion comprising soy bean oil, lecithin, glycerin and water.

142. (Previously Presented) The method of claim 150, wherein said solvent vehicle comprises glacial acetic acid, dimethylsulfoxide and an aqueous soy bean lipid emulsion comprising soy bean oil, lecithin, glycerin and water.

143. (Previously Presented) The method of claim 142, wherein said solvent vehicle comprises glacial acetic acid, dimethylsulfoxide, and an aqueous soy bean lipid emulsion comprising soy bean oil, lecithin, glycerin and water in a 2:6:3 volume ratio.

144. (Withdrawn) The method of claim 98, wherein said pharmaceutically acceptable aqueous solution comprises water.

145. (Withdrawn) The method of claim 98, wherein said pharmaceutically acceptable aqueous solution comprises saline solution.

146. (Withdrawn) The method of claim 98, wherein said pharmaceutically acceptable aqueous solution comprises dextrose solution.

147. (Withdrawn) The method of claim 146, wherein said dextrose solution comprises 5% to 70% dextrose in water.

148. (Withdrawn) The method of claim 147, wherein said dextrose solution comprises 5% or 10% dextrose solution.

149. (Withdrawn) The method of claim 98, wherein said secondary solvent comprises a parenteral infusion fluid.

150. (Previously Presented) The method of claim 97, wherein said solvent vehicle comprises glacial acetic acid and an aqueous lipid emulsion.